Originating Unit	[ ] Administration [ ] Alice! [ ] CPS [ ] Disability Services [ ] Patient Services [X] Medical Services [ ] Sexual Violence Response		
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SUBJECT: Vaccine Adverse Reaction Reporting Policy

SCOPE
Applies to all clinical staff in Medical Services.

POLICY
All vaccine related adverse events must be reported in a timely fashion to the Vaccine Adverse Event Reporting System (VAERS). VAERS is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The Columbia Health-specific form ADM-SAF 6 FORM 1 Adverse Incident and Near Miss Report Form should also be completed for all vaccine-related adverse events.

PROTOCOL

1. If a patient reports any adverse effect to a vaccine the following steps should be taken:
    a. If it is an immediate reaction, the emergency protocol should be followed (see PCMS-SO 1 Medical Management of Vaccine Reactions Policy). Once the appropriate care has been provided a VAERS form should be completed.
    b. If it is a late reaction, the provider should determine if the reaction is reportable, once appropriate care has been provided. A reaction is reportable to VAERS if there is any significant adverse event that occurs after the administration of any vaccine licensed in the United States. Any significant adverse event should be reported even if the provider is unsure whether a vaccine caused the event. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine, or any event listed in the reportable events table that occurs within the specified time period after vaccination (see attached). This document is also available in the references section of the electronic health record.

2. If it is determined that a report needs to be filed, the provider should take the following information:
    a. The patient's identifying data
    b. The date and time the vaccine(s) were given
    c. What vaccine(s) were given including the manufacturer, lot number, route/site, and how many previous doses were received.
    d. Whether any other vaccines given in the 4 weeks prior to the occurrence date
    e. Whether the patient on any other medications at the time
    f. The nature of the reaction

3. To file a report the form can be obtained from www.vaers.hhs.gov and can either be downloaded as a PDF file or completed online.

4. The original form is mailed or emailed to VAERS. One copy is placed on the chart or scanned into the electronic record. A second copy is given to the Executive Director of Medical Services, who will maintain a file of all vaccine related adverse events.

5. The clinician should also complete and submit the Adverse Incident and Good Catch Report form is described in ADM-SAF 6 Adverse Incidents and Good Catches.

RELATED POLICIES:

ADM-SAF 6 Adverse Incidents and Near Misses

PCMS –SO 1 Medical Management of Vaccine Reactions in Adult Patients

APPROVALS

[x] Senior Vice President	11/11/21 Date	[x] Executive Director, Medical Services	11/11/21 Date
[x] Executive Director, Counseling and Psychological Services	11/11/21 Date	[x] Executive Director, Disability Services	11/11/21 Date
[x] Executive Director, Alice! Health Promotion	11/11/21 Date	[x] Executive Director, Sexual Violence Response	11/11/21 Date
[x] Chief of Administration	11/11/21 Date		